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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,242	03/21/2001	Robert Haselbeck	ELITRA.011A	7191
210	7590	10/19/2005	EXAMINER	
MERCK AND CO., INC			GIBBS, TERRA C	
P O BOX 2000			ART UNIT	
RAHWAY, NJ 07065-0907			PAPER NUMBER	

1635

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/815,242

Applicant(s)

HASELBECK ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-12, 18-20, 29-31, 37, 39, 45-96, 98-101 and 103-105 is/are pending in the application.

4a) Of the above claim(s) 10, 11, 18-20, 29, 30, 37, 39, 70-76, 88, 98, 99, and 105 is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 31, 45-69, 77-87, 89-96, 100, 101, 103 and 104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is a response to Applicant's amendment and remarks filed August 1, 2005.

Claims 10-12, 18-20, 29-31, 37, 39, 45-96, 98-101, and 103-105 are pending in the instant application. Claims 12, 31, 58-68, 71-76, and 78-84 have been amended.

This application contains claims 10, 11, 18-20, 29, 30, 37, 39, 70, 88, 98, 99, and 105 drawn to an invention nonelected with traverse on March 4, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

It is noted that in Applicant's election filed March 4, 2003, Applicants elected SEQ ID NO: 1463 as the antisense sequence complementary to the *yphC* gene, SEQ ID NO: 12600 as the *yphC* gene product (polypeptide), and SEQ ID NO: 4228 as the *yphC* nucleic acid encoding the gene product (polypeptide). In the response filed August 1, 2005, Applicants have amended claims 71-76 to be directed to a different invention than the originally elected invention.

As amended, claims 71-76 are directed to an invention that is independent or distinct from the invention originally elected for the following reasons: In the amendment filed August 1, 2005, Applicants have amended claims 71-76 to recite SEQ ID NO:8502 as the nucleic acid encoding the gene product (polypeptide). Applicant has received an

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action on the merits for the originally elected invention, SEQ ID NO: 4228 as the *yphC* nucleic acid encoding the gene product (polypeptide), and therefore claims 71-76 are drawn to a non-elected invention.

In summary, claims 71-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Additionally, SEQ ID NOs. 521, 1390, 1845, 2782, 3283, 5021, 5283, 10251, 10689, 10969, 11370, 11955, 13518, 13703, 3966, 6154, 6592, 6872, 7273, 7857, 8502, 9420, and 9605 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on March 4, 2003.

Claims 12, 31, 45-69, 77-87, 89-96, 100, 101, 103, and 104 are examined on the merits.

### ***Claim Rejections - 35 USC § 112***

In the previous Office Action mailed May 3, 2005, claims 31, 45-69, 71-84 and 101 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This rejection is withdrawn** against claims 71-76 in view of Applicants amendment to these claims to recite nonelected subject matter. It is noted that claims 71-76 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. **This rejection is also withdrawn** against claims 31, 45-69,

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and 77 in view of the Examiner's reassessment of the claims. Specifically, the Examiner is withdrawing this rejection against claims 31, 45-69, and 77 because these claims do not recite antisense nucleic acids with varying degrees of sequence identity to SEQ ID NO:1463. **However, this rejection is maintained** against claims 78-84 for the reasons of record set forth in the previous Office Action mailed May 3, 2005.

### ***Response to Arguments***

In response to this rejection, Applicants argue that the descriptions of percent sequence identity and antisense activity provides sufficient structural and functional characteristics to demonstrate Applicants possessed the claimed subject matter. Applicants contend that percent identity provides an overall generic description based on a particular sequence that structurally distinguishes the nucleic acid from other nucleic acids. Applicants further contend that antisense activity provides a functional description limiting the overall structure of the nucleic acid based on sufficient complementarity base pairing to have antisense activity. Applicants point to the interim written description guidelines which specifically notes:

An applicant may also show that an invention is complete by disclosure of sufficiently detailed **relevant identifying characteristics** which provide evidence that applicant was in possession of the claimed invention, i.e., complete or **partial structure**, other physical and/or chemical properties, **functional characteristics** when coupled with a known or disclosed correlation between function and structure, or some **combination of such characteristics**.

Applicants argue that the skilled artisan need only perform routine testing of sequences within such descriptions to confirm that such sequences have the desired antisense

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activity and thus, it would not take undue experimentation to find appropriate antisense sequences to support the claims.

Applicant's arguments have been fully considered but are not found persuasive because contrary to Applicant's assertions, the Examiner disagrees that the descriptions of percent sequence identity and antisense activity provides sufficient structural and functional characteristics to demonstrate Applicants possessed the claimed subject matter. The Examiner is basing her argument on the fact that the mere recitation of a sought-for property of a nucleic acid cannot substitute for a description of the structure of those nucleic acids.

Because the claims are so broad, a great deal of experimentation would be needed to identify, use, and discover those sequences with any particular percentage identity to SEQ ID NO:1463 as referenced in the claims. The instant specification does not provide guidance as to which of the astronomical number of embodiments embraced by the claims might have the functional properties required in the claims. Further, there are no working examples of any nucleic acids with any particular percent identity to SEQ ID NO:14634 that carry out the properties required in the claims. With limited disclosure provided by the specification, the skilled artisan cannot envision those antisense nucleic acids with varying degrees of sequence identity to SEQ ID NO:1463, which reduces the activity of a gene product required for cellular proliferation, thereby producing a sensitized cell as recited in the instant claims. Therefore, only SEQ ID NO:1463, and not antisense nucleic acids with varying degrees of sequence identity to

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SEQ ID NO:1463, meets the written description provision of 35 U.S.C. 112, first paragraph.

### ***Double Patenting***

In the previous Office Action mailed May 3, 2005, claims 12, 31, 45-69, 71-87, 89-96, 100, 101, 103 and 104 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9 and 10 of U.S. Patent No. 6,720,139 ('139). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed May 3, 2005.

### ***Response to Arguments***

In response to this rejection, Applicants argue that the pending claims provide description of sequences and the rejection fails to indicate where the '139 patent claims such sequences.

Applicant's arguments have been fully considered but are not found persuasive. As argued in the previous Office Action mailed May 3, 2005, the methods claimed in the '139 patent fully embraces the methods as instantly claimed. For example, claim 1 of the '139 patent is drawn to a broad genus of *any* antisense nucleic acid, while the instant claims are drawn to a particular species of an antisense nucleic acid, namely SEQ ID NO:1463. Thus, the species of the instant application anticipates the genus of

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claim 1 of the '139 patent. Therefore, the methods claimed in the '139 patent embrace the methods as instantly claimed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.




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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg

October 13, 2005



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